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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,434	06/26/2003	Mark P. Anstadt	034448-007	5213
21839 7590 01/24/2008 BUCHANAN, INGERSOLL & ROONEY PC POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404			EXAMINER OROPEZA, FRANCES P	
			ART UNIT 3766	PAPER NUMBER
			NOTIFICATION DATE 01/24/2008	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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## Office Action Summary

Application No.

10/607,434

Applicant(s)

ANSTADT ET AL.

Examiner

Frances P. Oropeza

Art Unit

3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10/31/07 (RCE & Amendment).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 131-150, 153, 155-157, 159-162, 243 and 244 is/are pending in the application.
- 4a) Of the above claim(s) 132, 134-149, 156, 157 and 159-162 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 131, 133, 150, 153, 155, 243 and 244 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Request for Continued Examination*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. The Applicant's submission filed on 10/31/07 has been entered.

### *Response*

2. The Applicant at least amended independent claim 131 in the response filed 10/31/07, hence the rejection of record is withdrawn and a new rejection established in the subsequent paragraphs.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 131, 133, 150, 153, 155, 243 and 244 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner is unable to find support for a

“deformable” direct mechanical ventricular assistance apparatus (claim 131 and 234), in the instant specification. In the response filed 10/31/07, the Applicant identified pages 101, line 30 to page 102, line 16 of the specification as providing support for this amendment. The Examiner finds the citation identified by the Applicant supports a uniform expansion and contraction of the liner and not a deformable direct mechanical ventricular assistance apparatus. The only place the Examiner noted the word “deformable” was in reference to the material of construction for the seal (730) in Figure 18A (page 109, line 6). New matter may not be entered at this point in the prosecution. Appropriate correction is required.

*Claim Rejections - 35 USC § 103*

5. Claims 131, 133, 150, 153, 155, 243 and 244 are rejected under 35 U.S.C. 103(a) as being unpatentable over Easterbrook et al. (US 6238334) in view of Kung et al. (US 6626821).

Easterbrook et al. disclose a process/ deformable device for assisting the function of a heart, comprising a single deformable continuous cavity of variable volume extending circumferentially completely and continuously around the outer wall of the heart (204), and a controller importing the electrocardiogram signal into a pump with an accepted fluid pressure signal for use in an accepted controlling algorithm, accepted to be programmed by the physician (abstract; figure 27; col. 8 @ 13-34; col. 12 @ 56 – col. 13 @ 21; col. 14 @ 50 – col. 15 @ 35).

As discussed in the previous paragraph of this action, Easterbrook et al. disclose the claimed invention except the ventricular assist device using a controller to change volumes within the single continuous cavity of variable volume based on drive fluid flow rate,

Kung et al. flow balancing in a ventricular assist device using a controller to change volumes within the single continuous cavity of variable volume based on drive fluid flow rate for the purpose of varying the ventricular ejection volume. It would have been obvious to one having ordinary skill in the art at the time of the invention to have the controller effect changes in the volume within the single continuous cavity of variable volume based on the drive fluid flow rate in the Easterbrook et al. system in order to properly adjust the ventricular ejection volume to establish the right and left ejection pressures appropriate for the patient (col. 3 @ 58-61; col. 5 @ 16-28).

6. Claims 131, 133, 150, 153, 15, 243 and 244 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsitlik et al. (US 5971910) in view of Kung et al. (US 6626821).

Tsitlik et al. disclose a method and deformable apparatus for assisting the function of a heart, comprising a single deformable continuous cavity of variable volume extending circumferentially completely and continuously around the outer wall of the heart (36), and a controller importing the electrocardiogram signal into a vacuum pump with an accepted fluid pressure signal for use in an accepted controlling algorithm, accepted to be programmed by the physician (abstract; figure 1; col. 4 @ 47 – col. 5 @ 15; col. 5 @ 44-67; col. 11 @ 22-24).

As discussed in the previous paragraph of this action, Tsitlik et al. disclose the claimed invention except the ventricular assist device using a controller to change volumes within the single continuous cavity of variable volume based on drive fluid flow rate.

Kung et al. flow balancing in a ventricular assist device using a controller to change volumes within the single continuous cavity of variable volume based on drive fluid flow rate for

the purpose of varying the ventricular ejection volume. It would have been obvious to one having ordinary skill in the art at the time of the invention to have the controller effect changes in the volume within the single continuous cavity of variable volume based on the drive fluid flow rate in the Tsitlik et al. system in order to properly adjust the ventricular ejection volume to establish the right and left ejection pressures appropriate for the patient (col. 3 @ 58-61; col. 5 @ 16-28).

### *Specification*

7. The amendment filed 10/31/07 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows in quotations: “deformable” direct mechanical ventricular assistance apparatus (claims 131 and 234).

The Applicant is required to cancel the new matter in the reply to this Office Action.

### *Statutory Basis*

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (571) 272-4953. Fran's schedule typically is Monday and Tuesday 9AM-7PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. Carl's schedule typically is Monday, Wednesday, Friday 9AM-5 PM EST; Tuesday, Thursday 9AM-3PM and 9PM-11PM EST. The fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300 for regular communication and for After Final communications.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frances P. Oropeza  
Patent Examiner  
Art Unit 3766

*FPO*  
*1/17/08*

*Carl H. Layno*  
**CARL LAYNO**  
**PRIMARY EXAMINER**